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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,113	06/27/2003	Scott B. Bintrim	DAS-101XC2	6438
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SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			LUNDGREN, JEFFREY S	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/609,113	Applicant(s) BINTRIM ET AL.	
	Examiner Jeff Lundgren	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-41 is/are rejected.
- 7) ☒ Claim(s) 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>see office action</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions and Status of the Claims

Applicant's election *without traverse* of Group II, claim 2, in the reply filed on January 19, 2006, is acknowledged.

Applicants have cancelled claims 1-24, and presented new claims 25-41. Claims 25-41 are directed to the elected invention, and are examined on the merits.

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on September 29, 2003, June 23, 2004, November 22, 2004, and November 10, 2005, have been considered by the Examiner. The submission is in compliance with the provisions of 37 CFR § 1.97. Enclosed with this Office Action is a return-copy of the Form PTO-1449 with the Examiner's initials and signature indicating those references that have been considered.

Claim Objections

Claim 27 is objected to because the claim does not "further" comprise method steps in addition to those of claim 25, and for inappropriate grammar (*i.e.*, "for *an* ability to enhance *an* activity of ..."). Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 27 is indefinite for reciting the phrase “toxin complex toxin protein,” as this term does not appear to have definitive metes and bounds. This phrase does not appear to be a term of art, nor defined anywhere in the specification. Correction is required.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-41 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are directed to a method of screening for certain toxins, wherein the screening is directed to a plurality of identifying all of the pluralities from *Paenibacillus* isolates for toxin activity to lepidopteran and rootworm. Although Applicants have demonstrated that they have obtained certain toxins of this class, Applicants’ have not reasonably identified a substantial number of toxin species from the vast number isolates across all of the *Paenibacillus* species to demonstrate that Applicants had adequately described the genus.

In the Detailed Description of the Invention, Applicants state that their invention is directed towards unique biological alternatives for pest control. Applicants assert that the invention provides new sources of proteins that have toxin activity against insects, such as lepidopterans, and other similar pests, and relates to new sources of novel polynucleotides that can be used to encode such toxins, and to methods of making and methods of using the toxins and corresponding nucleic acid sequences to control insects and other like plant pests.

Although the claims are directed to the entire genus of *Paenibacillus* isolates and toxin proteins identified by the claimed method, Applicants examples are substantially narrower, and are directed to only a small number of protein species. Example 1 teaches one particular strain in the group of *Paenibacillus*, DAS1529, which was classified based on its 16S rDNA (Example 2),

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and demonstrated certain toxic effects towards the claimed lepidopteran, wherein the toxin was isolated (Examples 3 and 4), and the spectrum of activity disclosed for the *cry*-like toxin, Cry1529 (Table 10, page 65). Example 9 teaches the use of PCR primers for identifying Cry1529 homologues; Example 10 use DAS1529 as a combined toxin; Example 11 teaches stabilizing DAS1529 against trypsin; Example 12 is related to the design of certain PCR primers of IDAS1529; Example 13 demonstrates PCR amplification; Example 14 demonstrates the detection of homologues of IDAS1529; an Example 15 demonstrates the insecticidal activity of DB482.

However, the art teaches that due to many factors, that the limited number of species exemplified by Applicants' does not support the large and broad range of isolates and proteins claimed by Applicants. For example, Gardener (Gardener, *Phytopathology* 94(11):1252-1258 (2004)) teaches that there is great deal of genetic diversity between *Paenibacillus* species, and that a single strain (or limited number) couldn't possibly describe the genus adequately:

"Culture-independent analyses of soil DNA have confirmed the presence of easily cultured species and revealed additional, uncultured diversity in both the *Bacillus* and *Paenibacillus* rRNA lineages (7, 18, 21, 70). However, contradictory evidence exists on the relative abundance of cultured and uncultured representatives of these genera in different soils. Some reports indicated that the large majority of *Bacillus*-like sequences cloned from the soils(21, 70) were highly similar to know species. But, others report that the dominant *Bacillus* sequences present in a different soil are not the same as those present in easily cultured isolates (7, 18). Interestingly, the substantial effort leading to the isolation of this previously uncultured lineage (referred to as DA001) also led to the isolation of even more microdiversity that had not been previously directly detected in DNA clone banks of sequences obtained from the same soil (20)."

Gardener, at page 1252, col. 2, first full paragraph.

Also on point regarding Applicants' lack of adequate written description is the teaching of Crickmore (Crickmore *et al.*, *Microbiology and Molecular Biology Reviews* 62(3):807-813 (1998)). Crickmore teaches the complexities in identifying and characterizing the cry-isolates from bacteria such as *Bacillus* and related strains, and demonstrates that there is no common agreement in the art for how to classify the isolates (see pages 807-808).

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Therefore, Applicants have not adequately described their invention at the time it was claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-41, are rejected under 35 U.S.C. 102(b) as being anticipated by Warren *et al.*, PCT International Publication No. WO 94/21795, published on September 29, 1994.

Claim 25 is directed to a method of screening a plurality of different *Paenibacillus* isolates for toxin activity against lepidopteran and rootworm; claim 40 specifies lepidopteran and claim 41 specifies corn rootworm. Claim 28 is similar to claim 25, except the activity assay is instead the monitoring of the insect, and claim 29 requires a plurality of insects.

Through screening, Warren has identified *Bacillus* strains capable of producing pesticidal proteins and auxiliary proteins during vegetative growth, and the proteins are purified and genes encoding the proteins are cloned (see Examples 1-18). The proteins and the genes are useful in pest management programs, including lepidopteran (page 3, third paragraph; tobacco budworm in Table 14, page 32), and including rootworm (see Tables 1-10, especially Table 2, and see Example 3b). A *Bacillus cereus* isolate that was significantly active against corn rootworm was isolated and characterized. Culture supernatants were very active against Western and Northern corn rootworms and had an overall spectrum of activity that was different from that of endotoxins. Warren also teaches that there are a number of *Bacillus* species useful as pesticides, such as those listed in Table 11 on page 14, namely, *B. pulvifaciens*, and *B. macquariensis* (both are currently recognized as *Paenibacillus*; see Heyndrickx *et al.*, *International Journal of Systematic Bacteriology* 46(1):270-279 (1996), and print out from the internet having the domain address: www.dsmz.de/species/sp200231.html). Accordingly, claim 25 is anticipated.

In addition to the teachings of Warren that meet the limitations of claim 25, Warren observes a *plurality* of insects treated with toxin for 6 days (*i.e.*, the claimed observation; page

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31, top paragraph), as required by claims 28 and 29. Accordingly, claims 28 and 29 are also anticipated.

Claim 26 is directed to feeding a plurality of insects the toxin and observing (Warren's teaching of the Western, Northern and Southern corn rootworm in Example 3, as well as others listed in Example 3). Claim 36 is directed to feeding the toxin in agar, and claim 37 reads on proving protein within the agar on top of the plates (Warren, in Example 3, paragraph bridging pages 30 and 31). Claim 38 is directed to feeding an artificial diet of the protein in wells of a plate, and claim 39 is directed to feeding larvae (Warren, in Example 3 teaches dishes and larvae).

Claim 34 is directed to cell pellets, as taught by Warren (last paragraph of Example 2 on page 30); claim 35 is directed to "purified protein," as taught by Warren (Example 4, page 34); and claim 33 is directed to assaying for molecular weight of the protein in the sample, as taught by Warren (Example 4, page 35).

Claims 30-32 are directed to a library of clones, as taught by Warren (Example 9, pages 38-41). Claim 27 is directed to a "toxin complex toxin protein," as taught by Warren (Example 18, wherein the 80 kDa and/or 35 kDa protein are delivered singly or in combination).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. mResolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25-41 are rejected under 35 U.S.C. 103(a)¹ as being unpatentable over Warren *et al.*, PCT International Publication No. WO 94/21795, published on September 29, 1994.

Claims 25-41, are rejected under 35 U.S.C. 102(b) as being anticipated by Warren *et al.*, PCT International Publication No. WO 94/21795, published on September 29, 1994.

Claim 25 is directed to a method of screening a plurality of different *Paenibacillus* isolates for toxin activity against lepidopteran and rootworm; claim 40 specifies lepidopteran and claim 41 specifies corn rootworm. Claim 28 is similar to claim 25, except the activity assay is instead the monitoring of the insect, and claim 29 requires a plurality of insects.

Through screening, Warren has identified *Bacillus* strains capable of producing pesticidal proteins and auxiliary proteins during vegetative growth, and the proteins are purified and genes encoding the proteins are cloned (see Examples 1-18). The proteins and the genes are useful in pest management programs, including lepidopteran (page 3, third paragraph; tobacco budworm in Table 14, page 32), and including rootworm (see Tables 1-10, especially Table 2, and see Example 3b). A *Bacillus cereus* isolate that was significantly active against corn rootworm was isolated and characterized. Culture supernatants were very active against Western and Northern corn rootworms and had an overall spectrum of activity that was different from that of endotoxins. Warren also teaches that there are a number of *Bacillus* species useful as pesticides, such as those listed in Table 11 on page 14, namely, *B. pulvifaciens*, and *B. macquariensis* (both are currently recognized as *Paenibacillus*; see Heyndrickx *et al.*, and print out from www.dsmz.de/species/sp200231.html). Accordingly, claim 25 is anticipated.

In addition to the teachings of Warren that meet the limitations of claim 25, Warren observes a *plurality* of insects treated with toxin for 6 days (*i.e.*, the claimed observation; page 31, top paragraph), as required by claims 28 and 29. Accordingly, claims 28 and 29 are also anticipated.

¹ This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 26 is directed to feeding a plurality of insects the toxin and observing (Warren's teaching of the Western, Northern and Southern corn rootworm in Example 3, as well as others listed in Example 3). Claim 36 is directed to feeding the toxin in agar, and claim 37 reads on proving protein within the agar on top of the plates (Warren, in Example 3, paragraph bridging pages 30 and 31). Claim 38 is directed to feeding an artificial diet of the protein in wells of a plate, and claim 39 is directed to feeding larvae (Warren, in Example 3 teaches dishes and larvae).

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Claims 30-32 are directed to a library of clones, as taught by Warren (Example 9, pages 38-41). Claim 27 is directed to a "toxin complex toxin protein," as taught by Warren (Example 18, wherein the 80 kDa and/or 35 kDa protein are delivered singly or in combination).

Although Warren does not experimentally exemplify the isolates from *Paenibacillus*, one of ordinary skill in the art would have had a reasonable expectation of success in arriving at the invention as claimed because of Warren's suggestion of a limited number of bacterial strains in Table 11. One of ordinary skill in the art would have been motivated to select the claimed *Paenibacillus* because of the benefits that other strains demonstrate over certain other isolates of the Bt toxin. Therefore, the invention as a whole was prima facie obvious over the art of record at the time it was invented.

Conclusions

No claim is allowable.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsius verbis*, clarification on the record may be helpful). Should

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Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSL

JON EPPERSON, PH.D.
PATENT EXAMINER

